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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,318	07/31/2003	Marvin J. Slepian	F00397.70068.US	1899

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Boston, MA 02210

EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,318

Applicant(s)

SLEPIAN ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Priority

Applicant's requests for priority correction cannot be handled by the Office of Initial Patent Examination as requested by applicant since PCTUS89/03593 was never given Rule 371 status in the parent application and thus the PCT was never given national stage status. See patent 5,674,287 where applicant was given continuity to the PCT file by claiming it as a continuation. Since it is a continuation and not a 371 national stage application, applicant does not get benefit to the earlier US patent applications and the rejections in the case still stand. The examiner is consulting with the Office of PCT at this time for possible remedies to this situation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-9, 12-17, 28, 30, 32, 37-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Spears USPN 5,092,841.

Spears teaches the application of various prepolymeric materials including soluable polymers such as albumin that are crosslinked either by thermal energy or other known crosslinking and polymerizing techniques such as chemical polymerization. (See column 6 line 65) so as to form linings on arterial walls. The prepolymeric material may be heated and cooled (see column 10 lines 5-15) and is placed by a balloon that mechanically deforms the material to fit into cracks and fissures. (column 5 lines 40-46). Radiation may be used for heating (column 12 lines 35-44). The therapeutic agents include growth factors, antithrombotic agents (heparin), thrombolytic agents (column 7 lines 22-34) as well as alkylating, anti-proliferative agents (column 8 lines 22-34)and anti-inflammatory agents (steriodal and nonsteroidal) and monoclonal antibodies) (column 7 lines 28-34).

Claims 1, 5-8, 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Grubbs et al. USPN 4,919,151. Grubbs teaches the mixture of pre-polymers and photoinitiators that are reacted with light to photocrosslink the material into the shape of the eye capsule. Claim 1 reads as though the pre-polymeric material is the therapeutic agent and thus the examiner consider the pre-polymeric materials of Grubbs et al. to be the therapeutic agent.

Claims 1, 5-8, 10, 19, 37-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones USPN 4,978,391. Jones teaches the application of a prepolymer and a therapeutic agent to inner body parts including teeth which is formed into a laer and later activated by an actinic light to produce a hardened agent eluting material. A list of agents is found in column 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11, 18-27, 29, 31, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spears USPN 5,092,841. Applicant differs in the types of materials used such as the polymers or the specific species of drug genus that Spears teach useful for his stent. All of applicant's materials are well known materials for forming stent members as well as drugs for treating stenosis. Applicant's selection of materials known to be useful for treating stenosis would merely constitute an obvious design choice.

Claims 2-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al USPN 4,938,763 in view of Jones USPN 4,978,391 or Grubbs et al. USPN 4,919,151. Dunn teaches the application of various pre-polymeric materials along with a list of agents (column 6 lines 55+) for forming medicament releasing polymers in the body. Applicant differs in reciting the application of heat or light to the prepolymer so as to polymerize the material into its final shape. It was well known to apply light and heat to polymers to increase the polymerization time as evidenced by Grubbs and Jones. To have applied heat or light and the requisite materials to the Dunn prepolymer mixture would have been obvious at the time of applicant's invention.

Response to Arguments

Applicant's arguments filed 9-27-2004 have been fully considered but they are not persuasive. Applicant needs to petition to correct the continuity in the 5,674,287 patent so that he may obtain priority back to the 235,998 application to remove Spears as a reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3762


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

January 10, 2005


MARK BOCKELMAN
PRIMARY EXAMINER